K072972
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510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

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Olympia, WA. 98502
Telephone: 425-239-1240
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NOV - 6 2007

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems (PACS)
Proprietary Name:	MEDStreaming Medical Office
Classification Name:	Picture Archiving and Communications System, Class II

3) Device Description
The MEDStreaming Medical Office software provides a means of opening and displaying image files. The MEDStreaming Medical Office software provides a means of transferring medical image files using a DICOM network method from the modality acquisition devices to the MEDStreaming Medical Office server. MEDStreaming's Medical Office provides a means for transferring the acquired studies to a DICOM compliant archive device using standard networking methods.

The MEDStreaming Medical Office software provides a means to retrieve and view image data located on an acquisition or archive device using a standard network connection. The MEDStreaming Medical Office software provides a means for querying and retrieving patient studies from a networked DICOM server device.

The MEDStreaming Medical Office software provides a means of creating AVI, BMP and JPG graphic files from the image data displayed by the software.

The MEDStreaming Medical Office software provides a means of quantifying the image data using standard measurement tools.

The MEDStreaming Medical Office software provides a means of transferring the DICOM Structured Reporting components provided by a connected acquisition device. MEDStreaming's Medical Office provides a means of transferring labeled measurements using a serial gateway from modality devices that support a serial data transfer method.

MEDStreaming's Medical Office provides a means of generating an examination report for patient studies reviewed on the Medical Office workstation utilizing Microsoft standard text, spreadsheet and database programs.

MEDStreaming's Medical Office provides a means for exporting report results in HL7 or standard graphic file format.

MEDStreaming's Medical Office provides a method for generating utilization reports for data contained within the MEDStreaming patient database using standard Microsoft database tools.

4) Performance Standards
No performance standards for PACS systems or components have been issued under the authority of Section 514.

The MEDStreaming Medical Office software has been designed to comply with the following voluntary standards:

ISO Joint Photographic Experts Group (JPEG) Image Compression Standard
DICOM Standard 3.0
ICD-9 Finding Codes
Exam Type CPT Codes
Health Language 7
Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL)
Intersocietal Commission for the Accreditation of Echocardiographic Laboratories (ICAEL)
Microsoft Office Interoperability Engine

5) General Safety and Effectiveness Concerns
The device labeling contains operating instructions for the safe and effective use of the MEDStreaming Medical Office software.

6) Substantially Equivalent Devices
MEDStreaming LLC believes that the capability and features of the MEDStreaming Medical Office software makes it substantially equivalent to other image display products commercially available, specifically the ProSolv Cardiovascular Viewer, Analyzer and Server.

7) Software
Software development for the MEDStreaming Medical Office software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the software. Appropriate steps have been taken to control all identified risks for this type of image display and communication product.

8) Conclusions
The MEDStreaming Medical Office software is designed and manufactured to meet United States and international standards for the display and transmission of images acquired on medical imaging devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and image transmission within a clinical setting. The MEDStreaming Medical Office software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2007

MEDStreaming LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K072972
Trade/Device Name: MEDStreaming Medical Offices Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 20, 2007
Received: October 22, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072972

Device Name: ___ MEDStreaming Medical Office Software

Indications for Use:

The MEDStreaming Medical Office software provides a means of opening and displaying image files.
The MEDStreaming Medical Office software provides a means of transferring medical image files using a DICOM network method from the modality acquisition devices to the MEDStreaming Medical Office server.
MEDStreaming's Medical Office provides a means for transferring the acquired studies to a DICOM compliant archive device using standard networking methods.
The MEDStreaming Medical Office software provides a means to retrieve and view image data located on an acquisition or archive device using a standard network connection.
The MEDStreaming Medical Office software provides a means for querying and retrieving patient studies from a networked DICOM server device.
MEDStreaming's Medical Office provides a means to digitize video information from connected imaging modalities using a standard video digitizing engine.
The MEDStreaming Medical Office software provides a means of creating AVI, BMP and JPG graphic files from the image data displayed by the software.
The MEDStreaming Medical Office software provides a means of quantifying the image data using standard measurement tools.
The MEDStreaming Medical Office software provides a means of transferring the DICOM Structured Reporting components provided by a connected acquisition device.
MEDStreaming's Medical Office provides a means of transferring labeled measurements using a serial gateway from modality devices that support a serial data transfer method.
MEDStreaming's Medical Office provides a means of generating an examination report for patient studies reviewed on Medical Office utilizing Microsoft standard text, spreadsheet and database programs.
MEDStreaming's Medical Office provides a means for importing and exporting patient information in HL7 format.
MEDStreaming's Medical Office provides a method for generating utilization reports for data contained within the MEDStreaming patient database using standard Microsoft database tools.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072972